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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
DAHLE, CHUN WU	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,18 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, 18, 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on January 13, 2009, has been entered.

2. Applicant's amendment to the claims, filed January 13, 2009, has been entered.

Claims 1-6, 8, 10-17, 19-24, and 26-31have been canceled.
Claims 7, 9, 18, and 25 are pending and currently under consideration.

3. This Office Action is in response to Applicant's amendment to the claims and remarks filed on January 13, 2009.

The rejections of record can be found in the previous Office Actions, mailed on February 22, 2006, July 17, 2006, November 20, 2006, August 9, 2007, February 5, 2008, and August 14, 2008.

4. In view of applicant's cancellation of claims 20-23 and 26-29, the previous rejection under 35 USC 112, first paragraph, enablement, regarding "pharmaceutical formulation" is rendered moot.

5. In view of applicant's amendment to the claims, the previous rejection under 35 USC 112, first paragraph, written description, new matter, (regarding the negative limitation) has been withdrawn.

6. In view of the cancellation of claim 19, the prior rejection under 35 USC 103(a) (against claims 7 and 9) is rendered moot.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 7, 9, 18, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586, reference listed on PTO-892 mailed on February 22, 2006) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886, reference listed on PTO-892 mailed on February 22, 2006) for reasons of record set forth in the previous Office Actions mailed on February 22, 2006, July 17, 2006, November 20, 2006, and February 5, 2008.

Given that applicant has canceled the new matter "but does not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO:2" in amendment, filed on January 13, 2009, the withdrawn rejection has been reinstated herein.

Further, given that the claims have been accorded the priority of the applications 09/869,388 and PCT/US99/30004, which is 10/09/2001 and 12/29/1999, respectively, because the subject matter claimed in the instant application only has support under 35 U.S.C. 112 in priority applications 09/869,388 and PCT/US99/30004 but not in USSN 09/223,919, and 09/224,604. Specifically, insufficient support was identified for the limitation of "SEQ ID NOs: 6, 8, and 10" in USSNs 09/223,919 and 09/224,604. Thus, Adema et al. (WO 98/24906) is qualified as 102(b) type of prior art (see detailed analysis in previous Office Action mailed on February 22, 2006).

Adema et al. teach an isolated polypeptide of SEQ ID NO:2 isolated from monocyte wherein SEQ ID NO:2 is 80.4% identical to the claimed polypeptide of SEQ ID NO:6 (see

attached sequence alignment of record). Adema et al. further teach methods of making and using monoclonal antibodies using polypeptide having amino acid sequences of SEQ ID NO:2 as immunogen using techniques such as hybridoma and recombinant technology. Furthermore, Adema et al. teach that the antibody can be fragment such as Fab, Fv, and can be attached to solid support including beads, and be included in units such as a kit (e.g. see pages 4-6). Moreover, Adema et al. teach that the antibody can be formulated into a pharmaceutical composition with pharmaceutically acceptable carriers and be presented in unit dosage form for parenteral administration, including subcutaneous administration and intravenous administration (e.g. see page 4 and 22-45).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:2 is specific to the instant polypeptide with SEQ ID NO:6.

Applicant's arguments, filed on January 13, 2009, have been fully considered but have not been found persuasive.

Applicant argues that Adema et al. do not teach protein FDF03-S1 consisting of the amino acid sequence of SEQ ID NO:6 wherein said antibody or fragment thereof is in complex with said FDF03-S1 polypeptide.

This is not found persuasive for reasons of record. Given the high degree of sequence homology between the prior art polypeptide of FDF03 of SEQ ID NO:2 and instant FDF03-S1 consisting of SEQ ID NO:6, monoclonal antibody that binds to the prior art SEQ ID NO:2 would inherently bind shared regions of sequence identity of the instant polypeptide FDF03-S1 of SEQ ID NO:6.

Regarding the recited "wherein said antibody or fragment thereof is in complex with said DFD03-S1 polypeptide", it is noted that such recitation does not alter the structure of the claimed antibody. Claim scope is not limited by the wherein clause that does not limit a claim to a particular structure. See MPEP 2111.04. Here, given that the claimed antibody and the prior art antibody are identical or substantially identical in structure, the prior art antibody would inherently capable of being in complex with FDF03-S1 polypeptide that is 80.4% identical in amino acid sequence of the prior art FDF03 polypeptide with SEQ ID NO:2.

As such, applicant's arguments have not been found persuasive.

9. Claims 7, 9, 18, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. (US Patent Application 2005/0155089, reference on PTO-892 mailed on August 9, 2007) for reasons of record set forth in previous Office Action mailed on August 9, 2007) as evidenced by Campbell (Monoclonal Antibody Technology. 1985 Published by Elsevier Science Publishers. Chapter I, pages 1-32, reference of record).

As stated in previous Office Actions (e.g. the Office Action mailed on August 9, 2007), Lal et al. teach human signal peptide containing proteins including proteins with amino acid sequence of SEQ ID NO:7 that is 100% identical to the instant SEQ ID NO:6 (see paragraph [0041] and the sequence alignment of record). Lal et al. further teach purified antibodies that

bind human signal peptide containing protein of SEQ ID NO:7 including monoclonal antibodies, antibody fragments such as Fab, Fv, recombinant antibody, e.g. humanized antibody or fragment thereof, (see entire document, particular paragraphs [0074] and [0144]-[0153]). Lal et al. further teach that said antibody can form complex with the polypeptide antigen by interacting with said antigen (e.g. see paragraph [0087]).

As evidenced by Campbell, it is advantageous to use antibodies e.g. monoclonal antibody in basic research, diagnostics and therapeutic uses (see entire document, particularly pages 2-23). Further, Campbell teaches that it is customary now for any group working on macromolecule to both clone the genes coding for it and make monoclonal antibodies to it, sometimes without a clear objective for their application (e.g. see page28).

Therefore, the reference teachings anticipate the claimed invention.

Applicant's arguments, filed on January 13, 2009, have been fully considered but have not been found persuasive.

Applicant argues that Lal et al. does not disclose any specific and substantial utility of the peptide. Applicant argues that Lal et al. does not enable one of skill in the art to use the claimed antibody. Thus, applicant asserts that Lel et al. is not a proper 102(e) type reference.

This is not found persuasive for reasons of record. "The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112. In *In re Hafner*, 410 F.2d 1403 161 USPQ 783 (CCPA 1969), the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." *Id.* at 1405; *see Schoenwald*, 964 F.2d at 1124; *In re Samour*, 571 F.2d 559, 563-64 197 USPQ 1 (CCPA 1978). The reason is that

section 112 "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." *Hafner*, 410 F.2d at 1405; *see* 1 Donald S. Chisum, *Chisum on Patents* §3.04[1][c] (2002); *see also In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-52 64 USPQ2d 1202_ (Fed. Cir. 2001) (finding anticipation where applicant sought a patent based on a new use for a previously disclosed method).". Moreover, in order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. See MPEP 2122.

Here, given that the claimed antibody is enabled because the Lal et al. provide that SEQ ID NO:7 can be used as antigen to make antibody using well-known methods. Thus, the prior art antibody is enabled since the public is in possession of it.

Therefore, applicant's arguments have not been found persuasive.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Primary Examiner, Art Unit 1644